UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

23/APR/2013

MEMORANDUM: Acute Toxicity Data Evaluation Record (DER) for SYN19573 Herbicide

Subject:	Name of Pesticide Product:	SYN19573 Herbicide
	EPA File Symbol:	100-RUTN
	DP Barcode:	D407152
	Decision No.:	471359
	Action Code:	R310
	PC Codes:	122990 Mesotrione
		417300 Glyphosate

From: Tracy Keigwin, Biologist
Technical Review Branch
Registration Division (7505P)

To: Michael Walsh, RM Team 23
Herbicide Branch
Registration Division (7505P)

Applicant: Syngenta Crop Protection LLC
P.O. Box 18300
410 Swing Road
Greensboro, NC 27419-8300

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Glyphosate, N-(phosphonomethyl) glycine	3.4
Mesotrione	34.0
Other Ingredient(s):	62.6
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests a review of acute toxicity studies (MRIDs 48758803 (870.1100), 48758804 (870.1200), 48758805 (870.1300), 48758806 (870.2400), 48758807 (870.2500), and 48758808 (870.2600) submitted to support the registration of EPA File Symbol 100-RUTN, SYN19573 Herbicide. EPA File Symbol 100-RUTN is a post emergent herbicide for weed control in glyphosate tolerant (GT) corn. The registrant has stated that the

product is similar to EPA Reg. No. 100-1356; however the acute toxicity profile and precautionary language of EPA File Symbol 100-RUTN will be based on the submitted acute toxicity studies.

GLP: All studies were conducted in accordance with GLP.

DEFICIENCIES: None

COMMENTS AND RECOMMENDATIONS:

1) The 6 submitted studies are acceptable.

2) TRB notes that the proposed PPE on the product label is reflective of category II acute dermal toxicity and/or category II primary dermal irritation. EPA File Symbol 100-RUTN is Category IV for these routes of exposure. While the labeled PPE of EPA File Symbol 100-RUTN is similar to that of the EPA Reg. No. 100-1356, the product specific acute toxicity data which the registrant has submitted dictates the precautionary language and PPE. If the registrant is aware of a reason that category II dermal PPE must be on the product label, the registrant should discuss with the PM for further clarification.

2) The registrant has included some voluntary precautionary language and First Aid statements. This is acceptable.

3) The product chemistry team must approve the proposed CSFs (basic and 6 alternate formulations) before this action can be finalized.

LABELING: This product is category IV for the acute toxicity routes of exposure listed above. Precautionary and first aid statements are not required; however the proposed precautionary and first aid statements that appear on the submitted product label are acceptable. Note that the "Keep out of Reach of Children" statement must also remain on the product label. In addition, the registrant must have a baseline PPE of a long sleeve shirt, long pants, shoes and socks, as stated in Chapter 10 of the label review manual. In addition, the following information must appear on the product label:

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Reviewer: Tracy Keigwin **Date:** April 23, 2013
Risk Manager (EPA): 23

The following table is the Acute Toxicity Data Evaluation Record (DER) for the six studies submitted for the proposed product, EPA File Symbol 100-RUTN:

1. DP BARCODE: 407152				
2. PC CODES: 122990 and 417300				
3. CURRENT DATE: April 23, 2013				
4. TEST MATERIAL: Mesotrione/Glyphosate SC (044.81/448.12)(A19573B; Batch ID 639837; EPSL Reference Number 120209-8H; Mesotrione: 3.37(wt/wt) or 45 g/L and Glyphosate: 34.1 (%wt/wt) or 455 g/L; Beige-colored liquid, Density: 1332 g/L)				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity / rat EPSL (Dayton, NJ) Study #33923/June 6, 2012 OCSPP 870.1100; OECD 425	48758803	LD_{50} Females > 5000 mg/kg bw. All 3 survived. Two animals exhibited soft feces, diarrhea, ano-genital staining, reduced fecal volume and/or ataxia, recovering by day 3. No gross abnormalities observed at necropsy.	IV	A
Acute dermal toxicity / rat EPSL (Dayton, NJ) Study #33924/June 6, 2012 OCSPP 870.1200; OECD 402	48758804	LD_{50} > 5000 mg/kg bw (both sexes and combined). All survived. All exhibited erythema and edema at the dose site between days 1 and 9, with 1/5 males and 4/5 females additionally exhibiting desquamation and 1/5 females exhibiting a green discoloration at the dose site. No gross abnormalities observed at necropsy.	IV	A
Acute inhalation toxicity / rat EPSL (Dayton, NJ) Study #33925/June 6, 2012 OCSPP 870.1300; OECD 403	48758805	LC_{50} > 2.53 mg/L (nose-only; gravimetric; both sexes and combined). Mean MMAD and GSD: 2.65 µm and 2.22. All survived. All animals exhibited abnormal respiration following exposure to the test substance, but recovered by study day 3.	IV	A

		All males (5/5) and 2 females (2/5) failed to gain or lost BW between Days 1 and 3, but increased BW thereafter. No gross abnormalities observed at necropsy.		
Primary eye irritation / rabbit EPSL (Dayton, NJ) Study #33926/June 6, 2012 OCSPP 870.2400; OECD 405	48758806	There was no corneal opacity or iritis. All (3/3) exhibited grade 2 redness and grade 1-2 chemosis at the one hour observation, with all scores zero at 24 hours. MMTS = 11.3 at one hour.	IV	A
Primary dermal irritation / rabbit EPSL (Dayton, NJ) Study #33927/June 6, 2012 OCSPP 870.2500; OECD 404	48758807	PDI is 0.0 (non-irritating). No erythema or edema was observed at any dose site during the study.	IV	A
Dermal sensitization (Buehler)/Guinea Pig EPSL (Dayton, NJ) Study #33928/June 6, 2012 OCSPP 870.2600; OECD 406	48758808	Not a dermal sensitizer. 100% test substance used for both induction and challenge phases. No positive response (grade 1 or higher) was observed in any of the test or naïve control animals at the 24 and 48 hour challenge observation. Grade 1 erythema was observed in 3/10 positive control (100% α-HCA) animals at the 24 hour observation, continuing in 1/10 animals at the 48 hour observation.	Neg	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap